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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,962	10/30/2003	James R. Casciani	009103-009740US	8826

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EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,962

Applicant(s)

CASCIANI ET AL.

Examiner

Matthew J. Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-69 is/are pending in the application.
- 4a) Of the above claim(s) 61 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60, 62-64 and 66-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/6/05; 10/18/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The listing of claim received with the Response to the Restriction/Election Requirement filed on 5/26/2005 was non-compliant because the text of withdrawn claim 65 was not included in the listing. The elected claims were still examined by the Examiner but the Applicant should correct this oversight in future correspondence in this Application.

Election/Restrictions

2. Claims 61 and 65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/26/2005. It is noted that the Election/Restriction Requirement mailed on 3/21/2005 erroneously listed claim 61 as generic when the claim clearly is included in species A, which is the nonelected species. Thus, claim 61 was withdrawn from consideration as being directed to a nonelected species.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 60 and 63-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 14-15 of U.S. Patent No. U.S. Patent 6,662,033 to Casciani et al. (Casciani).

In regard to claim 60 of the present application, claim 3 of Casciani claims an oximeter sensor that includes "at least one light source" for emitting light; a detector for "detecting light subsequent to being scattered by...tissue, the light including an infrared light spectrum, said infrared spectrum having a range useful for measuring oxygen saturation in a patient with high saturation, the detected light also including a red light spectrum, said red light spectrum having a mean wavelength between 700 and 790 nanometers"; and limiting "light signals received at the detector from the light source to no more than three spectra". Although the conflicting claims are not identical, they are not patentably distinct from each other because the components of the claimed apparatus of claim 3 of Casciani when used in their proper manner would carry out the method steps of claim 60 of the present application. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made that using the apparatus of claim 3 of Casciani would result in the method of claim 60 of the present application.

In regard to claim 63 of the present application, claim 14 of Casciani claims an oximeter sensor that includes "at least one light source" for emitting light; a detector for detecting "light from the light source after scattering by...tissue"; and limiting "light signals received at the detector from the light source to no more than three spectra, a first spectrum including 735 nanometers at an intensity of at least 50% of the intensity of any other wavelengths in said first spectrum". Although the conflicting claims are not identical, they are not patentably distinct from each other because the components of the claimed apparatus of claim 14 of Casciani when used in their proper manner would carry out the method steps of claim 63 of the present application. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made that using the apparatus of claim 14 of Casciani would result in the method of claim 63 of the present application. In regard to claim 64 of the present application, claim 15 of Casciani claims "wherein a second spectrum has a mean wavelength of from 805 to 940 nm used, in conjunction with said first spectrum, for measuring oxygen saturation in a patient".

5. Claims 60, 62, and 66-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 5-7 of U.S. Patent No. U.S. Patent 6,272,363 to Casciani et al. (Casciani).

In regard to claims 60 and 62 of the present application, claim 3 of Casciani claims an oximeter sensor that includes "at least one light source" for emitting light; a detector for detecting "light from the light source after scattering by...tissue"; and limiting

“light signals received at the detector to only first and second spectra (thus no more than three spectra are received at the detector), a first spectrum having a mean wavelength in the infrared range of from 805 to 940 nm used conventionally for measuring oxygen saturation in a patient with high blood saturation, and a second spectrum having a mean wavelength of from 700 to 790 nm (a red light spectrum) used, in conjunction with said first spectrum, for measuring oxygen saturation in a patient”. Although the conflicting claims are not identical, they are not patentably distinct from each other because the components of the claimed apparatus of claim 3 of Casciani when used in their proper manner would carry out the method steps of claims 60 and 62 of the present application. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made that using the apparatus of claim 3 of Casciani would result in the method of claims 60 and 62 of the present application.

In regard to claim 66 of the present application, claim 3 of Casciani claims an oximeter sensor that includes “at least one light source” for emitting light; a detector for detecting “light from the light source after scattering by... tissue”; and limiting “light signals received at the detector to only first and second spectra, a first spectrum having a mean wavelength in the infrared range of from 805 to 940 nm used conventionally for measuring oxygen saturation in a patient with high blood saturation, and a second spectrum having a mean wavelength of from 700 to 790 nm used, in conjunction with said first spectrum, for measuring oxygen saturation in a patient”. Although the conflicting claims are not identical, they are not patentably distinct from each other because the components of the claimed apparatus of claim 3 of Casciani when used in

their proper manner would carry out the steps of claim 66 of the present application.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made that using the apparatus of claim 3 of Casciani would result in the method of claim 66 of the present application.

In regard to claim 67 of the present application, claim 5 of Casciani includes the use of a fetal sensor for sensing fetal tissue. In regard to claim 68 of the present application, claim 6 of Casciani claims "wherein said second spectrum is used for calculating oxygen saturation for saturations below 80%". In regard to claim 68 of the present application, claim 7 of Casciani claims "wherein said second spectrum is used for calculating oxygen saturation for saturations below 65%".

6. Claim 63 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. U.S. Patent 5,421,329 to Casciani et al. (Casciani).

In regard to claim 63 of the present application, claim 9 of Casciani claims a "method for measuring blood oxygen saturation, comprising... selecting a light source (for emitting light) and a light detector (for detecting light scattered by tissue)... receiving at said detector only red and infrared portions of said spectrum (which inherently means no more than three spectra are detected)". (claim 1 of Casciani from which claim 9 depends). Claim 9 of Casciani also claims a spectrum that includes "735 nanometers at an intensity of at least 50% of the intensity of any other wavelengths in said... spectrum". (claim 9 of Casciana). Although the conflicting claims are not identical, they are not

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patentably distinct from each other because claim 9 of Casciani claims a method that is narrower in scope than the method of claim 63 of the present application. Claim 9 of Casciani meets all the limitations set out in claim 63 of the present application and it would be obvious that one who is practicing the method of claim 9 of Casciani is actually practicing the method of claim 63 of the present invention.

7. Claims 60 and 63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 9 of U.S. Patent No. U.S. Patent 5,421,329 to Casciani et al. (Casciani).

In regard to claim 60 of the present application, claim 8 of Casciani claims a "method for measuring blood oxygen saturation...comprising...selecting a light source (for emitting light) and a light detector(for detecting light scattered by tissue)...receiving at said detector only red and infrared portions of said spectrum (which inherently means no more than three spectra are detected) including a portion between 700 and 790 nanometers" (claim 1 of Casciani from which claim 8 depends). Claim 8 of Casciani also claims "a first spectrum within said infrared spectrum in a range useful for a patient having high saturation". (claim 8 of Casciani). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 8 of Casciani claims a method that is narrower in scope than the method of claim 60 of the present application. Claim 8 of Casciani meets all the limitations set out in claim 60 of the present application and it would be obvious that one who is practicing the method of claim 8 of Casciani is actually practicing the method of claim 60 of the present invention.

In regard to claim 63 of the present application, claim 9 of Casciani claims a "method for measuring blood oxygen saturation...comprising...selecting a light source (for emitting light) and a light detector(for detecting light scattered by tissue)...receiving at said detector only red and infrared portions of said spectrum (which inherently means no more than three spectra are detected)" (claim 1 of Casciani from which claim 9 depends). Claim 9 of Casciani also claims a spectrum including "735 nanometers at an intensity of at least 50% of the intensity of any other wavelengths in said...spectrum". (claim 9 of Casciani). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 9 of Casciani claims a method that is narrower in scope than the method of claim 63 of the present application. Claim 9 of Casciani meets all the limitations set out in claim 63 of the present application and it would be obvious that one who is practicing the method of claim 9 of Casciani is actually practicing the method of claim 63 of the present invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 60 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 3,638,640 to Shaw. Shaw teaches an oximeter that includes emitting light from at least one source (10, 12, 14); detecting light from detectors (47, 49, 51); the detectors are limited to detecting about the 660, 715, and 805 nm wavelengths. (column 2, lines 31-70 of Shaw).

10. Claims 60, 62, 66 and 68-69 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,402,778 to Chance. Chance teaches an oximeter that uses 754 nm and 816 nm wavelengths, light sources, and a light detector. (Fig. 2 and column 5, lines 3-40 of Chance).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

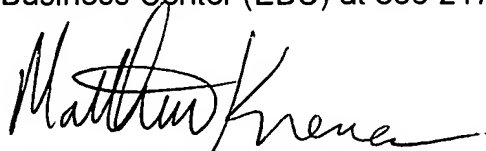
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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